**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| **IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAs) PRODUCTS LIABILITY LITIGATION** | **CIVIL ACTION** |
| **THIS DOCUMENT RELATES TO:** <br> ***ALL ACTIONS / ALL CASES*** | **MDL No. 3094** <br> **2:24-md-03094-KSM** |

**DEFENDANT ELI LILLY AND COMPANY'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO SUPPLEMENT THE RECORD AS TO CROSS CUTTING ISSUE NO. 1**

On July 23, 2025—more than two months after the May 2025 Rule 702 evidentiary hearings and oral arguments on Issue 1—Plaintiffs moved to supplement the Issue 1 record with a document that Lilly had produced to Plaintiffs *nearly one year ago*, in September 2024.

Plaintiffs point to one sentence in an October 2023 Lilly submission to the FDA, which they claim "belie[s]" Lilly's position. ECF No. 447-1 at 2. Plaintiffs are wrong. That sentence says gastroparesis "is documented by physician diagnosis, evaluating GE with scintigraphy, or symptoms and retained food at endoscopy." ECF No. 447-2 at 18. But the fact that doctors sometimes *document* gastroparesis without a gastric emptying study (GES) is not new. It was the very reason for Issue 1 in the first place—to determine whether a doctor's documentation is sufficient without objective testing.

Plaintiffs ignore that the same document reiterates that gastroparesis "requires" delayed gastric emptying, and that another section titled "Diagnosis" states that gastroparesis "commonly is diagnosed by gastric scintigraphy." ECF No. 447-2 at 15, 18. This is consistent with Lilly's

position that objective testing is required for a reliable diagnosis that satisfies Rule 702, and it also aligns with consensus guidelines from all major U.S. and international societies and other leading authorities. These guidelines and authorities recognize that a reliable gastroparesis "diagnosis cannot be made without objective evidence of delayed gastric emptying."[1]

The Motion thus fails at the outset because it is premised on the incorrect claim that the document shows Lilly "revers[ed] its previous position." ECF No. 447-1 at 2-3. Separately, the Motion is untimely and contrary to the expert focus of Issue 1. The Court should deny the Motion.

**BACKGROUND**

In August 2024, the Court prioritized as Issue 1 whether "to reliably diagnose a patient with gastroparesis[,] the clinician would have to have performed objective testing, such as a gastric emptying study (GES), at the time symptoms presented." CMO 18, ECF No. 235 at ¶ 4. The Court recognized that Issue 1 "is going to be decided based on [the] experts," and adopted a schedule for expert discovery and Rule 702 briefing. 8.8.24 Hr'g, ECF No. 227 at 16; *see also* 7.12.24 Hr'g, ECF No. 224 at 30; CMO 19, 21, ECF Nos. 269, 291.

In parallel with the Issue 1 expert work, the parties engaged in company discovery on Issues 2 (warning adequacy and federal preemption) and 3 (general causation). *See* CMO 20, ECF No. 282. As part of that discovery, on September 27, 2024, Lilly produced the document that is the subject of Plaintiffs' Motion. ECF No. 447-2. On November 18, 2024, Plaintiffs disclosed and submitted reports from Dr. Daniel Raines (a gastroenterologist) and Dr. Eliot Siegel (a radiologist). ECF Nos. 361-5, 361-4. Neither expert cited nor relied on this document. *Id.*; ECF Nos. 361-9, 361-10. Nor did they suggest they needed this kind of document to form their opinions. *Id.* As

[1] ECF No. 385 at 1 (emphasis added; quoting ECF No. 385-2, Camilleri, et al., *Pharmacologic treatments for gastroparesis*, Pharm. Revs., 77:10019 at 2 (Mar. 2025)).

Plaintiffs' counsel told the Court, their "experts don't need [company discovery] to proceed to offer their opinions and the methodologies" for diagnosing gastroparesis. 8.8.24 Hr'g, ECF No. 227 at 9:3-10:2, 11:16-21, 15:7-9.

By April 2025, the parties had submitted more than 3,700 pages of briefing and exhibits on Issue 1. ECF Nos. 359, 360, 361, 377, 379, 385, 386, 399. The extensive discovery and briefing record was punctuated by an evidentiary hearing on May 14, 2025 and oral argument on May 19, 2025. All three experts (two for Plaintiffs and one for Defendants) testified in examinations that stretched into the evening, and the parties presented hundreds of slides to help digest the massive record. *See* ECF Nos. 413, 419, 421; *see also* ECF Nos. 408, 409, 411.

Issue 1 is ripe for a decision, which will help frame Issues 2 and 3. On July 23, 2025, Plaintiffs filed this Motion to supplement the record with a document that has been in their possession for almost a year. ECF No. 447.

## ARGUMENT AND AUTHORITIES

### I. The Document Is Consistent With (And Does Not "Belie") Lilly's Position.

The Court should deny the Motion because the proposed supplemental document is neither contrary to nor a basis to estop Lilly from advancing its scientifically and legally correct positions.

**Plaintiffs' selected sentence is not contrary to Lilly's position here**. Plaintiffs' estoppel and relevance arguments rely on one part of a single sentence in the document. But their chosen statement that gastroparesis "is documented by physician diagnosis, evaluating GE with scintigraphy, or symptoms and retained food at endoscopy" does not "belie" Lilly's position here. ECF No. 447-1 at 2; ECF No. 447-2 at 18. Recognizing that doctors sometimes *document* gastroparesis in the context of symptoms and retained gastric food does not mean that symptoms or retained food can *reliably diagnose* gastroparesis under Rule 702.

As Lilly explained early on, "[w]hile clinicians may forego testing if a '*treatment* would have been the same regardless of [the] cause,' the real-world practice 'does not diminish the importance of [objective testing] for determining the *cause* of the symptoms in court.'" ECF No. 361-1 at 20 (quoting *Hoeflng v. U.S. Smokeless Tobacco Co., LLC*, 576 F. Supp. 3d 262, 282-83 (E.D. Pa. 2021) (original emphasis)); *see also* ECF No. 385 at 10 ("[A]ssessments in medical practice for purposes of treatment do not always align with reliable diagnostic or causation opinions in a legal setting. A symptom-based approach may work for some non-condition-dependent *treatment* decisions, but Plaintiffs are suing about the *diagnosis* of the specific condition of gastroparesis"); *see also id.* at 6, 11; ECF No. 411-1 at Slide 63.

**Other parts of the same document reinforce the importance of objective testing.** The sentence on which Plaintiffs rely appears in a section of the document titled "Delayed Gastric Emptying and Gastroparesis in Patients with T2DM." Plaintiffs do not mention that another part of the same section states that gastroparesis "requires" delayed gastric emptying. ECF No. 447-2 at 18. Plaintiffs also ignore other sections of the same document, including (1) a statement under the bolded "**Diagnosis**" heading that gastroparesis "commonly is diagnosed by gastric scintigraphy"; and (2) statements under the bolded heading "**Differential diagnosis for the symptoms**" that "nausea and vomiting are nonspecific with a wide variety of differential diagnoses," and that an array of conditions "could pose a very similar presentation to gastroparesis." *Id.* at 15-16. Thus, the document is consistent with and supports Lilly's position that symptoms of gastroparesis are non-specific; overlap with many other conditions; and do not alone reliably indicate delayed gastric emptying or gastroparesis. *See* ECF No. 447-2 at 16; ECF No. 361-1 at 1, 5-7, 15; ECF No. 385 at 2-3, 7-9; ECF No. 411-1 at Slides 16-18, 43-47, 57-59; ECF No. 411-2 at Slide 3.

Further, Plaintiffs ignore the sentence immediately after the one quoted in their Motion (bolded below), which confirms the important role gastric-emptying evaluation plays in diagnosing gastroparesis:

> Gastroparesis is identified only in people who are presented for care, and it is documented by physician diagnosis, evaluating GE with scintigraphy, or symptoms and retained food at endoscopy. **People in whom GE has not been evaluated may not have it diagnosed.**

ECF No. 447-2 at 18. In other words, without evaluating gastric emptying, it is not possible to diagnose gastroparesis, regardless of how a patient's doctor documents their symptoms.

**The document is not contrary to the scientific consensus that retained gastric food is not a reliable indicator of delayed gastric emptying.** The sentence's reference to documenting gastroparesis in some patients with retained gastric food (RGF) does not support Plaintiffs' position that RGF is a reliable method to assess delayed gastric emptying and diagnose gastroparesis under Rule 702. As explained in the parties' briefing and the May hearings, multiple articles and consensus statements recognize that gastroparesis cannot be diagnosed based on the presence of retained food on endoscopy. *See* ECF No. 411-1 at Slides 22-37. And the American College of Gastroenterology "specifically noted that '[r]etained gastric food (RGF) is frequently identified' during stomach examinations and cautioned that this 'should not be deemed to be diagnostic of GP.'" ECF No. 385 at 5.[2]

**Regulatory estoppel does not apply.** Finally, Plaintiffs' suggestion that Lilly's regulatory submission estops it from taking legally valid and scientifically supported positions in this litigation is frivolous. To start, Plaintiffs have not shown that Lilly has "taken a position in the litigation opposite to the one presented to the regulatory agency." *In re Suboxone (Buprenorphine*

[2] Quoting Camilleri, Michael et al. *ACG Clinical Guideline: Gastroparesis*, 117 Am. J. of Gastroenterology 1197, 1202 (2022), doi:10.14309/ajg.0000000000001874, ECF No. 361-13.

*Hydrochloride & Naloxone) Antitrust Litig.*, 2017 WL 4810801, at *9 (E.D. Pa. Oct. 25, 2017). As shown above, Lilly's position "in the current litigation" is not "opposite to its position to the [FDA]." This is not a case of "playing 'fast and loose' with the judicial system.'" *Kessler Dental Assocs., P.C. v. Dentists Ins. Co.*, 505 F. Supp. 3d 474, 479 (E.D. Pa. 2020). Lilly "takes the same position here today" as it did to the FDA in 2023. *Id.* at 480.[3] This should end the estoppel inquiry.

In any event, Plaintiffs do not explain how regulatory estoppel—which is applied rarely and usually in certain state-law cases involving insurance policy exclusions, and which many courts have expressly rejected—is available to resolve the Issue 1 federal evidentiary question.[4] Lilly has not identified any case applying regulatory estoppel as Plaintiffs propose to do here.[5]

## II. There Is No Good Cause To Supplement The Record With A Document Produced Nearly A Year Ago.

The Court should deny the Motion also because there is no good cause to supplement the record with a document that was produced and has been available to Plaintiffs for nearly a year.

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[3] *See also 1800 Farragut Inc. v. Utica First Ins. Co.*, 2021 WL 4243435, at *7 (E.D. Pa. Sept. 16, 2021) (Marston, J.) (regulatory estoppel did not apply where "the representation allegedly made to regulators" was "the same argument subsequently made by the insurer in litigation.").

[4] *See, e.g., Chattanooga Pro. Baseball LLC v. Nat'l Cas. Co.*, 2022 WL 171936, at *3 (9th Cir. Jan. 19, 2022) (no authority adequately supporting "the proposition that federal law recognizes regulatory estoppel"); *SyderGeneral Corp. v. Great Am. Ins. Co.*, 928 F. Supp. 674, 682 (N.D. Tex. 1996) ("The regulatory estoppel argument has been rejected by virtually every other state and federal court to address the issue"), *aff'd*, 133 F.3d 373 (5th Cir. 1998); *In re Erie COVID-19 Bus. Interruption Prot. Ins. Litig.*, 2022 WL 7933018, at *32 n.28 (W.D. Pa. Oct. 14, 2022).

[5] This is not surprising. Regulatory standards may be different than evidentiary requirements in civil litigation. A "regulatory agency such as the FDA may choose to err on the side of caution," but courts must "engage in objective review of evidence to determine whether it has sufficient scientific basis to be considered reliable." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1249–50 (11th Cir. 2005). *See also, e.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 174 F. Supp. 3d 911, 923–24 (D.S.C. 2016).

*First*, the Court has emphasized that Issue 1 "is going to be decided based on [the] experts." 8.8.24 Hr'g, ECF No. 227 at 15:25-16:1, 16:8-9. The Court already "decided this issue after fulsome discussion," and "full[] consider[ation] by the Court after it was repeatedly raised and argued by counsel." *See* ECF No. 276 at 9.[6] Plaintiffs' Motion to supplement so the Court can consider a company document on which no expert relied is contrary to these prior rulings.

*Second*, Plaintiffs cannot justify introducing new evidence and argument long after the time for doing so expired. The Rule 16(b) good cause requirement "focuses on the diligence of the party seeking the modification of the scheduling order." *Shrieves v. Philadelphia Facilities Mgmt. Corp.*, 2020 WL 7240450, at *5 (E.D. Pa. Dec. 8, 2020) (Marston, J.). Plaintiffs have not shown any diligence. Their brief acknowledges the document "was produced prior to the May 14, 2025 hearing," ECF No. 447-1 at 2, but it does not disclose the document was produced way back in September 2024—*more than seven months* prior to the May 14, 2025 hearing.

And Plaintiffs' claim that they "only recently identified these statements relevant to cross cutting issue no. 1 during extensive preparation that is currently occurring for numerous upcoming depositions of Lilly personnel," ECF No. 447-1 at 2, is insufficient. They have "not identified with specificity" when or how they became aware of the document, nor have they explained how they were "unable, with diligence, to find that information before the deadline in the Court's Scheduling Order." *Weisberg v. Weisberg*, 2020 WL 4015239, at *3 (E.D. Pa. July 16, 2020) (Marston, J.) (denying motion to amend deadline to add parties despite plaintiffs claim that "it was not until reviewing discovery responses" "and assembling relevant information related to discovery

[6] Plaintiffs refer to their December 2024 request to delay the May 2025 hearing, pending additional company discovery. ECF No. 447-1 at 2 n.4 (quoting ECF No. 303). But they do not mention that the Court rejected their request, 12.17.24 Hr'g, ECF No. 339, at 14:5-11, or that they already had the October 2023 document for months by the time they made the request.

responses," that plaintiff "recognized the potential claim for contribution and/or indemnification"). This should be "the death knell" for the Motion. *See Doe v. Hosp. of Univ. of Pennsylvania*, 2021 WL 2671791, at *9 n.10 (E.D. Pa. June 29, 2021) (Marston, J.) (denying motion to modify schedule based on materials plaintiff "received *before* the amendment deadlines expired in this case") (original emphasis).[7]

**CONCLUSION**

The Court should reject Plaintiffs' attempt to supplement the record with a document (1) that was produced almost one year ago, (2) upon which no expert relied, and (3) that is consistent both with Lilly's position and the extensive record the Court already has before it. Nothing in the Motion (or the document itself, should the Court decide to consider it) can cure Plaintiffs' failure to satisfy their Rule 702 burden on Issue 1. Lilly respectfully requests the Court deny this Motion.

[7] *See also Rivlin v. Biomet*, 2021 WL 4477001, at *1 (E.D. Pa. Sept. 30, 2021) (Marston, J.) (denying Rule 702 motion as untimely where party did not give "any justification for missing the deadline listed in the Court's Scheduling Order, let alone demonstrated good cause.").

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 28, 2025, a true and correct copy of the foregoing Response to Plaintiffs' Motion to Supplement the Record as to Cross Cutting Issue No. 1 was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record.

*/s/ Samuel W. Silver*
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